IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

In re: Rosuvastatin Calcium Patent Litigation	:	
	:	MDL No. 08-1949
AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha,	:	
Plaintiffs,	:	
v.	:	Civ. No. 07-805-JJF-LPS
Mylan Pharmaceuticals Inc.,	:	
Defendant.	:	
AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha,	:	
Plaintiffs,	:	
v.	:	Civ. No. 07-806-JJF-LPS
Sun Pharmaceutical Industries Ltd.,	:	
Defendant.	:	

AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha,	:	
Plaintiffs,	:	
	:	Civ. No. 07-807-JJF-LPS
v.	:	
Sandoz Inc.,	:	
Defendant.	:	

AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha,	:	
Plaintiffs,	:	
	:	Civ. No. 07-808-JJF-LPS
v.	:	
Par Pharmaceutical Inc.,	:	
Defendant.	:	

AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha,	:	
Plaintiffs,	:	
	:	Civ. No. 07-809-JJF-LPS
v.	:	
Apotex Inc. and Apotex Corp.,	:	
Defendants.	:	

AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs, v. Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc., Defendants.	:	Civ. No. 07-810-JJF-LPS
AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs, v. Cobalt Pharmaceuticals Inc. and Cobalt Laboratories Inc., Defendants.	:	Civ. No. 07-811-JJF-LPS
AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs, v. Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc., Defendants.	:	Civ. No. 07-359-JJF-LPS

AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha,	:	
Plaintiffs,	:	
	:	Civ. No. 08-426-JJF-LPS
v.	:	
Teva Pharmaceuticals USA, Inc.,	:	
Defendant.	:	

REPORT AND RECOMMENDATION REGARDING MOTIONS FOR SUMMARY JUDGMENT AND TO DISMISS, AND ORDER ON EVIDENTIARY MOTIONS

This multidistrict litigation consolidates nine actions for patent infringement filed by Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha (collectively "AstraZeneca" or "Plaintiffs") against Defendants Mylan Pharmaceuticals, Inc. ("Mylan"), Sun Pharmaceutical Industries, Ltd. ("Sun"), Sandoz, Inc. ("Sandoz"), Par Pharmaceutical, Inc. ("Par), Apotex Inc. ("Apotex Inc.") and Apotex Corp. ("Apotex Corp."), Aurobindo Pharma Ltd. ("Aurobindo India") and Aurobindo Pharma, USA Inc. ("Aurobindo USA"), Cobalt Pharmaceuticals Inc. and Cobalt Laboratories Inc. ("Cobalt"), and Teva Pharmaceuticals USA, Inc. ("Teva") (collectively "Defendants"). (MDL No. 08-1949 D.I. 1)[1] AstraZeneca holds all substantial rights in U.S. Reissue Patent RE37,314 (the "'314 patent"). Each of the Defendants is purported to be involved in some way with the filing of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug

[1]All citations to the docket in the remainder of this Report & Recommendation are to the docket in MDL No. 08-1949, unless a different case number is provided in the citation.

Administration ("FDA"). The matter has been referred to me for all purposes through and including the pretrial conference. *See* Civ. No. 07-805 (D.I. 9).

Pending before the Court are three motions for summary judgment, a renewed motion to dismiss, and two motions to exclude expert testimony. I held oral argument on the pending motions on November 16, 2009. *See* Transcript of Nov. 16, 2009 Hearing (D.I. 387) (hereinafter "Tr."). Below I provide my recommendations with respect to the case-dispositive motions for summary judgment and dismissal and rule on the two motions relating to expert testimony.

A. Motion for Summary Judgment of Noninfringement and No Subject Matter Jurisdiction

Defendant Aurobindo USA has filed a Motion for Summary Judgment of Noninfringement and No Subject Matter Jurisdiction. (D.I. 277). In its motion, Aurobindo USA argues that it did not "submit" the Aurobindo ANDA and, thus, there is no case or controversy involving Aurobindo USA and the patent-in-suit. Hence, there is no subject matter jurisdiction. Plaintiffs respond that there is evidence to support a finding that Aurobindo USA acted as the authorized agent of Aurobindo India, the undisputed ANDA applicant, and, therefore, did "submit" the ANDA within the meaning of the applicable statute.

I considered this issue earlier in this case in connection with certain Defendants' (including Aurobindo USA) motion to dismiss. In my November 24, 2008 Report and Recommendation ("R&R"), I recommended denial of the pertinent motion to dismiss – a recommendation that was later adopted by Judge Farnan over the Defendants' objection. (D.I. 13; D.I. 78; D.I. 79) In my earlier R&R, I stated:

> [Congress'] goals are furthered by treating a wholly-owned subsidiary of a foreign

> ANDA applicant, which signs an ANDA as the agent of its parent-applicant, and which intends to benefit directly if the ANDA is approved – by participating in the manufacture, importation, distribution, and/or sale of the generic drug – as subject to suit under § 271(e) as one who has "submitted" an ANDA.

(D.I. 13 at 22)

I further remarked:

> My conclusions are in accord with those of the two courts that have considered this same question and have held that entities similarly-situated to . . . Aurobindo USA have "submitted" an ANDA. *See Wyeth*, 505 F. Supp. 2d at 306-07 ("[W]hen a wholly-owned U.S. subsidiary of a foreign corporation exists to distribute foreign-produced generic drugs in the U.S. and is actively involved in the ANDA process, the subsidiary also 'submits' an ANDA application."); *Aventis*, 403 F. Supp. 2d at 492-94 (permitting § 271(e)(2) claims to proceed against foreign parent as well as against its wholly-owned U.S. subsidiary that countersigned ANDA and appeared to be parent's U.S. marketing arm).

(*Id.* at 24)

Consistent with the precedents I cited, Judge Robinson recently held in *Cephalon, Inc. v. Watson Pharms., Inc.*, 629 F. Supp. 2d 338, 349 (D. Del. April 3, 2009), that, taking certain allegations as true, a subsidiary that would be involved in the marketing and distribution of the generic product that was the subject of an ANDA would be treated as having "submitted" the ANDA. Judge Robinson explained:

> "It shall be an act of infringement to submit" an ANDA to the FDA seeking approval "to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." 35 U.S.C. § 271(e)(2); *see also Wyeth v. Lupin Ltd.*, 505 F. Supp. 2d 303, 305 (D. Md. 2007). Parties "actively involved" in preparing the ANDA are deemed to have "submit[ted]" the ANDA, regardless of whether they are the named applicant; this is especially true where the parties involved are in the same corporate family. *Id.* at 306-07; *see also Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, 403 F. Supp. 2d 484, 492-94 (E.D. Va. 2005). "Active involvement" includes "marketing and distributing the approved generic drugs in the United States." *Wyeth*, 505 F. Supp. 2d at 306; *see also Aventis*, 403 F. Supp. 2d at 492-93.

> [Defendants] move to dismiss . . . on the grounds that they did not "submit" the ANDA. Accepting plaintiffs' allegations as true, however, the court concludes that [Defendants] did "submit" the ANDA. As described above, each took part in . . . and contributed employees to the various teams responsible for preparing the ANDA, and employees of each prepared and executed ANDA-related documents. Moreover, each will be involved in the marketing and distribution of the generic fentanyl buccal tablets if the ANDA is approved. These allegations are sufficient to raise [Defendants'] active involvement in the preparation of the ANDA above the speculative level. Accordingly . . . [Defendants'] motions to dismiss are denied.

Cephalon, 629 F. Supp. 2d at 349 (internal footnote omitted).

I continue to hold the views I expressed in my earlier R&R. I find further support for these conclusions in *Wyeth*, *Aventis*, and now *Cephalon*. The record before me contains evidence from which a reasonable finder of fact could find that Aurobindo USA: is a wholly-owned subsidiary of a foreign ANDA applicant (Aurobindo India); it signed the ANDA as an agent of its parent-applicant; and it intends to benefit directly if the ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the generic drug that is the subject of the ANDA. There is a genuine dispute of fact with respect to at least one of these factors: whether the former Aurobindo USA employee who signed Aurobindo India's ANDA signed in his capacity as an employee of Aurobindo USA (and therefore on behalf of Aurobindo USA) or rather whether he signed in his personal capacity (and therefore directly as Aurobindo India's agent, cutting Aurobindo USA out of the process). The circumstances surrounding the signature are disputed. Clearly, however, Aurobindo USA is not entitled to judgment as a matter of law. Accordingly, I recommend denial of the motion for summary judgment.

B. Motion for Summary Judgment of No Personal Jurisdiction and for Dismissal for Nonjoinder

Defendant Aurobindo India has filed a Motion for Summary Judgment of No Personal Jurisdiction and for Dismissal for Nonjoinder. (D.I. 275) By this motion, Aurobindo India moves for summary judgment that this Court lacks personal jurisdiction. Aurobindo India further argues that if it is no longer part of this case, then Aurobindo USA must also be dismissed as a defendant, given the absence of the necessary and indispensable Aurobindo India. Plaintiffs respond that personal jurisdiction exists in Delaware over Aurobindo India or, at a minimum, genuine material issues of fact exist as to personal jurisdiction. Plaintiffs further contend there is no basis to dismiss Aurobindo USA.

Aurobindo India made essentially the same arguments in a motion to dismiss. In my November 2008 R&R, I recommended denial of Aurobindo India's motion to dismiss without prejudice to its renewal after discovery. (D.I. 13 at 30) Although Aurobindo India has styled the pending motion a motion for summary judgment, the issue of personal jurisdiction is generally more appropriately resolved by a motion to dismiss. *See Marten v. Godwin*, 499 F.3d 290, 295 (3d Cir. 2007) ("Dismissing a claim for lack of personal jurisdiction is more appropriately done by way of Rule 12(b)(2) of the Federal Rules of Civil Procedure, rather than Rule 56."). That is true here, particularly given that, by Aurobindo India's acknowledgment, "no new material facts" came out in the discovery that followed issuance of my R&R. (Tr. at 105-06) Thus, I will treat Aurobindo India's motion as a renewed motion to dismiss for lack of personal jurisdiction. *See, e.g., United Dairy Farmers Co-op Ass'n v. Milk Control Commission of Comm'n of Commonwealth of Pa.*, 47 F.R.D. 1, *2-3 (W.D. Pa. May 14, 1969) ("Defendants' responsive

pleading is in the form of a Motion to Dismiss or for Summary Judgment . . . . What we really have is a Rule 12 motion to dismiss which raises . . . lack of jurisdiction over the persons of defendants. . . .").

Determining the existence of personal jurisdiction requires a two-part analysis. First, the Court analyzes the long-arm statute of the state in which the Court is located. *See Intel Corp. v. Broadcom Corp.*, 167 F. Supp. 2d 692, 700 (D. Del. 2001). Next, the Court must determine whether exercising jurisdiction over the defendant in this state comports with the Due Process Clause of the Constitution. *See id.*

In analyzing the motion, Aurobindo India urges the Court to consider *Forest Laboratories, Inc., v. Cobalt Laboratories, Inc.*, 2009 WL 605745 (D. Del. Mar. 9, 2009) ("*Forest Labs*"), *adopted by* 2009 WL 2753427 (D. Del. Aug. 27, 2009), insisting the instant case is "remarkably" and "strikingly similar" to *Forest Labs*. (D.I. 276 at 9-10) I have accepted Aurobindo India's invitation, but I conclude that the comparison to *Forest Labs* is not a favorable one for Aurobindo India. As Plaintiffs well state:

> [In *Forest Labs*,] the Delaware subsidiary corporation . . . was only a "shell" that did not perform any business activities, not the distributor of the parent's products as Aurobindo USA is for Aurobindo India. [Another] subsidiary in *Forest Labs,* [the one] which signed the parent's ANDA as the filing agent, was a New Jersey corporation, not a Delaware corporation like Aurobindo USA. Significantly, in *Forest Labs* this Court considered the fact that the parties denying jurisdiction in Delaware had not commenced any legal actions or proceedings in Delaware and had not been named as Defendants in any Delaware actions, whereas at least Aurobindo India has counterclaimed in this very courthouse.[[2]]

---

[2]Plaintiffs point out that Aurobindo India has participated in two ANDA suits in Delaware, and that in one of those multi-defendant ANDA cases, it did not contest jurisdiction in Delaware for the stated reasons of promoting judicial efficiency and conserving resources (*see Sanofi-Aventis v. Actavis South Atlantic LLC*, Civ. No. 07-572-GMS), and went on to assert counterclaims there. (D.I. 321 at 13)

> Moreover, the foreign parent's subsidiaries [involved in *Forest Labs*] did not even sell or distribute any products anywhere in the U.S. In the current case, Aurobindo USA is Aurobindo's U.S. marketing arm and U.S. distributor. Finally, the Plaintiff in *Forest Labs* did not have a principal place of business in Delaware, while the Plaintiff AstraZeneca Pharmaceuticals LP does here.

(D.I. 321 at 23)

In *Forest Labs*, I also found a lack of evidence to support treating the Delaware subsidiary – which, as noted above, was a "shell" that would not have been involved in distribution of the generic product and did not sign the foreign parent's ANDA – as either the agent or alter ego of its foreign ANDA-applicant parent. *See* 2009 WL 605745, at *5, 11. "Under the alter ego or piercing the corporate veil doctrine, courts will ignore the corporate boundaries between parent and subsidiary if fraud or inequity is shown. The agency theory, by contrast, examines the degree of control which the parent exercises over the subsidiary." *Applied Biosystems Inc. v. Cruachem, Ltd.*, 772 F. Supp. 1458, 1463 (D. Del. 1991). Here, by contrast, there is evidence from which a reasonable factfinder could find fraud or inequity or a sufficient degree of control over Aurobindo USA by Aurobindo India.

Plaintiffs summarize the alter ego evidence as follows:

> An Aurobindo USA Vice President, Mr. Prasada Kambham, signed the rosuvastatin ANDA that Aurobindo USA submitted to the FDA, certifying its accuracy and promising to update the application as necessary. Specifically, Mr. Kambham signed the application and also a two-page attachment detailing and introducing the ANDA submission, using his Aurobindo USA corporate contact information. He also included an email address and telephone number that the Aurobindo Defendants now contend were personal, although the allegedly personal nature of those contacts was never conveyed to the FDA. Signing the ANDA was no ministerial act. Instead, signing constituted a certification to the FDA under threat of criminal prosecution as to the truth and accuracy of the information presented therein and reflected assuming a duty to supply subsequently developed information regarding, for example, safety issues.

> On October 29, 2007, the FDA faxed a letter to Aurobindo USA explicitly referring to the corporation as the "U.S. Agent for: Aurobindo [India]." That letter was addressed to Aurobindo USA's corporate offices. On January 23, 2008, the FDA faxed another letter to Aurobindo USA, again referring to it as the "U.S. Agent to [Aurobindo India]," for the attention of Mr. Kambham. In early 2008, Mr. Kambham did not even work at Aurobindo USA. Nobody from Aurobindo India or Aurobindo USA wrote back to the FDA with an explanation that Mr. Kambham was the actual U.S. agent, not Aurobindo USA, as the Aurobindo Defendants would now have this Court believe.
>
> . . .
>
> The Aurobindo Defendants represented to the FDA that Aurobindo USA was Aurobindo India's filing agent, the FDA relied on that representation, and the Aurobindo Defendants did nothing to make the FDA believe otherwise.
>
> Aurobindo India is attempting to unfairly use a Delaware corporation, Aurobindo USA, to directly harm another Delaware corporation, Plaintiff AstraZeneca Pharmaceuticals LP, while trying to dictate a forum other than Delaware. The Aurobindo Defendants attempt to forum shop by representing Mr. Kambham's signature in one way to the FDA, and another to this Court, is inequitable and unjust. . . .

(D.I. 321 at 13-14, 22-23) (internal citations omitted)

Likewise, a reasonable factfinder could conclude that Aurobindo USA is Aurobindo India's agent from the following evidence of Aurobindo India's control over Aurobindo USA:

> Aurobindo India formed Aurobindo USA as its U.S. marketing arm and indeed, all of the products Aurobindo USA sells are manufactured by Aurobindo India. After forming Aurobindo USA, Aurobindo India continued to closely control and dominate Aurobindo USA by including Aurobindo India directors, officers, and executives on Aurobindo USA's board of directors. The Chairman of Aurobindo India has routinely appointed those board members to the board of Aurobindo USA. The overlap is so substantial that the board of directors for Aurobindo USA has never met – it has never even voted on a chairman. Instead, the Chairman of Aurobindo India directs the corporate strategy for Aurobindo USA and makes primary decisions without input from Aurobindo USA with respect to real estate transactions, financial decisions, delegation of manufacturing and other corporate-related responsibilities, and even the spinning off of subsidiaries from Aurobindo USA. Even more specifically, Aurobindo India routinely directed

> Aurobindo USA to file numerous ANDAs, including the ANDA at issue in this case.

(*Id.* at 16-17) (internal citations omitted)

There is sufficient evidence in the record from which a reasonable factfinder could conclude that Aurobindo USA "engages in [a] persistent course of conduct" in Delaware, thereby establishing general jurisdiction. 10 Del. C. § 3104(c)(4). For example, Aurobindo USA is incorporated in Delaware and is registered to sell pharmaceuticals in Delaware. (D.I. 322 Ex. 2 at 63 & Ex. 6) Aurobindo USA distributes and sells Aurobindo India's products in Delaware (and elsewhere in the U.S.), including through national retailers with a presence in Delaware. (D.I. 322 Ex. 10 at 61-62)

Under the alter ego and agency theories, these jurisdictional contacts of Aurobindo USA may be imputed to Aurobindo India. *See Minnesota Mining and Mfg. Co. v. Eco Chem, Inc.*, 757 F.2d 1256, 1265 (Fed. Cir. 1985) ("[A] court which has jurisdiction over a corporation has jurisdiction over its alter egos."). Therefore, there is evidence from which a reasonable factfinder might conclude that the requirements of Delaware's long-arm statute and the Due Process Clause[3] are satisfied. In sum, there are genuine disputes of material fact regarding whether this Court may exercise personal jurisdiction over Aurobindo India. Accordingly, I recommend that Aurobindo India's motion for summary judgment (and its related request that Aurobindo USA be dismissed)

---

[3]With respect to the due process inquiry, I agree with Plaintiffs: "Aurobindo India could [have] reasonably expect[ed] to be haled into Court when they decide[d] to challenge the patent that is protecting a blockbuster drug of a company that is based here in Wilmington. And who do they use to file it? Their Delaware corporation." (Tr. at 122) Additionally, given Aurobindo India's prior experience litigating at least one other ANDA patent case in Delaware – in which both Aurobindo defendants appeared voluntarily – Aurobindo India should reasonably have expected that a likely outcome of the filing of their rosuvastatin calcium ANDA would be litigation here in the District of Delaware.

be denied. *See generally Rice v. Nova Biomedical Corp.*, 38 F.3d 909, 915 (7th Cir. 1994) ("Certainly, if it is infeasible or inconvenient to make a definitive determination of personal jurisdiction on the basis of affidavits or other evidence presented in a pretrial hearing, the district judge can, as with other preliminary questions, defer resolution to the trial."); *see also* D.I. 78 at 6, 7 & n.4 (Judge Farnan, in affirming November 2008 R&R, suggesting that jurisdictional issues may not be amenable to resolution on summary judgment and trial may be required).

C. Apotex's Renewed Motion to Dismiss for Lack of Personal Jurisdiction or in the Alternative to Transfer

Defendant Apotex Inc. has renewed its Motion to Dismiss for Lack of Personal Jurisdiction or in the Alternative to Transfer to the Middle District of Florida.[4] (D.I. 307). I have concluded that there are insufficient contacts between Delaware and Apotex Inc. and, therefore, this Court lacks personal jurisdiction over this defendant. However, I also find that dismissal would be inappropriate and, instead, that transfer is warranted. Accordingly, I recommend that as to Apotex Inc. this action be transferred and the motion to dismiss be denied.

Plaintiffs argue that there is "general jurisdiction" over Apotex Inc. pursuant to 10 Del. C. § 3104(c)(4). "'[G]eneral' jurisdiction [is that jurisdiction] in which the defendant's contacts have no necessary relationship to the cause of action." *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1562 n.10 (Fed. Cir. 1994). For general jurisdiction to be present, a defendant must have continuous and systematic contacts with the forum state. *See Helicopteros*

[4]Although the title of the motion indicates an alternative desire to transfer the cause of action to the Middle District of Florida, Apotex Inc. has modified that request and now requests, if the case is to be transferred, transfer to the Southern District of Florida or the Northern District of Illinois. (Tr. at 136)

Nacionales de Colombia, S.A. v. Hall, 466 U.S. 408, 414-15 (1984).

Apotex Inc. is a Canadian corporation with a principal place of business in Canada. It has no offices, facilities, telephone listings, bank accounts, or property in Delaware. It does not have employees, or do business, in Delaware.

Nonetheless, Plaintiffs assert two bases for finding personal jurisdiction over Apotex Inc. in Delaware. First, Plaintiffs rely on Apotex Inc.'s repeated participation in litigation in this District. That is:

> Apotex Inc. – despite still contesting jurisdiction *in this particular case* – continues to repeatedly consent to the general jurisdiction of courts in this District in ANDA infringement cases instigated by its own filings, effectuating a clear business model. Apotex Inc. has now accepted the jurisdiction of courts in this District in thirteen cases in the last six years, representing over thirteen percent of the ANDA litigations in which it has been a party nationwide since 2002.

(D.I. 360 at 3; *see also id.* at 16-19, 26-32; Tr. at 140-41.) However, as Apotex Inc. observes, as a defendant it has had no choice as to where it was ultimately sued. Filing a counterclaim and defending a lawsuit, and consensually participating in other cases, is not enough to serve as a basis for a finding of a general presence in Delaware for all cases or a permanent waiver of a defendant's right to contest jurisdiction.

Next, Plaintiffs contend that Apotex Inc. controls Apotex Corp., so that Apotex Corp.'s contacts with Delaware should be imputed to Apotex Inc. This is the same "agency theory" of jurisdiction discussed above in connection with the Aurobindo Defendants. Here, however, I reach a different conclusion. I find that Plaintiffs have failed to meet their burden to demonstrate that Apotex Inc. exercises sufficient control over Apotex Corp. to establish a principal-agent relationship. Apotex Corp. generates its own revenue, with which it purchases the products it

sells. Apotex Corp. decides which of Apotex Inc.'s approved products it will market. Apotex Corp. pays Apotex Inc. for administrative services rendered by Apotex Inc. and the two companies maintain distinct books, records, financial statements, and tax returns. While there is some overlap between Apotex Inc. and Apotex Corp. in terms of directors and officers, the record does not establish that Apotex Inc. controls the day-to-day operations of Apotex Corp.

In sum, then, the record does not demonstrate continuous and systematic contacts between Apotex Inc. and Delaware. Plaintiffs have failed to meet their burden to establish personal jurisdiction.[5]

However, rather than dismissing the suit against Apotex Inc., the appropriate consequence for the lack of jurisdiction in this instance is to transfer to a district in which there is personal jurisdiction. Pursuant to 28 U.S.C. § 1631, I recommend transferring this action as to Apotex Inc. to the Southern District of Florida (where Apotex Inc. concedes jurisdiction exists), as this resolution is in the interest of justice and preserves the 30-month stay of FDA approval of Apotex Inc.'s ANDA. *See Forest Labs*, 2009 WL 605745, at *14. Plaintiffs filed suit in the District of Delaware in the good-faith belief that Apotex Inc. was amenable to litigating here, based on Apotex Inc.'s conduct in other litigation in this District. Accordingly, transfer is in the public interest. *See generally Pfizer Inc. v. Apotex, Inc.*, 2009 WL 2843288, at *3 (D. Del. Aug. 13, 2009) ("Courts have routinely held that both judicial economy and the interest of justice favor transfer where transferring a case would obviate a substantial question regarding personal jurisdiction. . . . Here, we find that substantial, unresolved questions remain with regard to

[5]Having found insufficient contacts with Delaware to satisfy the requirements of Delaware's long-arm statute, there is no need to reach the second-step constitutional question of whether exercise of jurisdiction here would violate the defendant's due process rights.

whether this District has personal jurisdiction over Defendant Apotex Inc.").[6]

D. Motion for Summary Judgment of No Inequitable Conduct

Plaintiffs have filed a Motion for Summary Judgment of No Inequitable Conduct. (D.I. 281) I recommend denial of this motion.

To prove inequitable conduct, an accused infringer must present clear and convincing evidence of both materiality and intent. *See Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008). Here, for purposes of Plaintiffs' motion, there is no dispute that the prior art references that were withheld from the PTO were material, so the issue in dispute is the evidence relating to intent.

As Judge Jordan explained in *Ampex Corp. v. Eastman Kodak Co.*, 460 F. Supp. 2d 569, 570 (D. Del. 2006):

> [C]harges of inequitable conduct are particularly ill-suited to resolution by summary judgment, because they often involve questions of intent and materiality. . . . The question of intent is especially problematic because, intent being a subjective state of mind, the proof requires the fact finder to evaluate all the facts and circumstances in each case. Such an evaluation is *rarely* enabled in summary proceedings.

(Internal citations and quotation marks omitted)

Here, as in *Ampex*, intent is "hotly contested." I agree with Defendants that there is conflicting testimony and that relevant documents are subject to varying interpretations. Among the genuine issues of material fact are: why did Plaintiffs' employee Kitamura leave her employment and, had she not done so, would she have disclosed the prior art at issue? why did

---

[6]Defendant requests that the Court strike Plaintiffs' Exh. 61 because the subject matter is irrelevant and prejudicial. (D.I. 369 at 1-2) Given my conclusion that no personal jurisdiction exists, I deny this request to strike as moot.

Plaintiffs' Shibata stamp and hold onto for weeks (rather than place into the appropriate file, as appears to have been his usual practice) copies of European Search Reports referencing the withheld prior art? why, evidently unlike for any other of Plaintiffs' patents, was responsibility for prosecuting the U.S. patent invested in a different individual than the one concurrently responsible for prosecuting the European patent? It may well be, as Plaintiffs assert, that the non-disclosures here were due to mistake and inadvertence, but making a final determination on this matter will require the factfinder to assess the credibility of the witnesses. There is evidence in the record from which a reasonable factfinder could conclude, by the requisite clear and convincing standard, that one or more individuals working for the Plaintiffs intended not to disclose material prior art to the PTO. Consequently, I recommend denial of Plaintiffs' summary judgment motion. *See Baker Oil Tools, Inc. v. Geo Vann, Inc.*, 828 F.2d 1558, 1566 (Fed. Cir. 1987) ("If the facts of materiality or intent are reasonably disputed the issue is not amenable to summary disposition.").

E. Motion to Exclude the Expert Testimony of Mami Hino

Defendants have filed a Motion to Exclude the Expert Testimony of Mami Hino. (D.I. 292). By this motion, Defendants seek to exclude Ms. Hino's testimony under *Daubert* and Federal Rule of Evidence 702. I will grant this motion.

The admissibility of expert testimony is a question of law governed by Rule 702 of the Federal Rules of Evidence and the Supreme Court's decision in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). Rule 702 governs the admissibility of expert testimony, subject to the relevancy provisions of Rules 401 through 403. Pursuant to Rule 702, in order to be admissible, expert testimony must "assist the trier of fact to understand the evidence or to determine a fact in

issue." The Supreme Court has assigned "to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert*, 509 U.S. at 597.

Defendants argue that Hino's expert "opinions" are really arguments, assumptions, and inferences as to the supposed state of mind or intent of Ms. Kitamura and her colleagues at Shionogi. I agree and therefore exclude Hino's testimony.

Generally, expert witnesses are not permitted to testify regarding "intent, motive, or state of mind, or evidence by which such state of mind may be inferred." *Oxford Gene Tech., Ltd. v. Mergen Ltd.*, 345 F. Supp. 2d 431, 443 (D. Del. 2004). In *Oxford*, there were:

> several instances in [the expert's] report which could be interpreted as referring to or inferring [the defendant's] state of mind, including: referring to [the defendant] "recognizing" that its business activities might infringe the [] patent, that [the defendant] may "feel" that a license is necessary, that [the defendant] may have been "concerned," and that [the defendant] had "concluded" whether it infringed or not.

Id. at 443 n.9 (internal citations omitted); *see also, e.g., AstraZeneca LP v. TAP Pharm. Prods., Inc.*, 444 F. Supp. 2d 278, 293 (D. Del. 2006) (expert not permitted to present "evidence by which such state of mind may be inferred"); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004) ("Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony.").

While Plaintiffs deny offering Hino's expert opinions as evidence of Kitamura's state-of-mind or intent to deceive the PTO, they acknowledge that they are offering Hino's opinions as "circumstantial evidence relating to [Kitamura's] intent." (D.I. 325 at 13) Plaintiffs argue that

this inferential expert evidence of intent is appropriate because Hino's opinions are only a "frame of reference for the Court's intent inquiry," that is, "the Court's inquiry into whether there was an intent to deceive the USPTO." (*Id.* at 13, 17) It appears to me, however, that Hino does seek to testify to her conclusions as to Kitamtura's intent. *See, e.g.*, D.I. 294 Ex. 9 at ¶88 ("[I]t is my opinion that . . . Ms. Kitamura apparently did not recognize any patentability defect . . . and . . . had Ms. Kitamura remained at Shionogi, she would have submitted to the USPTO the EPO search report later received . . . .").[7] Such testimony should be excluded. *See, e.g., Novartis Pharms. Corp. v. Teva Pharms. USA, Inc.*, 2009 WL 3754170, at *8 (D.N.J. Nov. 5, 2009) (determining that, while expert "w[ould] be permitted to testify with respect to the underlying facts regarding the prosecution of the . . . patent applications, his testimony w[ould] not be permitted to address the mental states of the patentees . . . [and] is not permitted to draw inferences from the underlying facts or opine with respect to the intent of such parties in presenting these applications.").

While it might be possible to parse through Hino's 98-paragraph report and find something not excludable, this is not a task the Court should have to undertake in the first instance. I will exercise my discretion and exclude Hino's testimony in its entirety.[8]

F. Motion to Exclude the Expert Testimony of Dr. William R. Roush

Defendants seek to exclude certain portions of Dr. Roush's testimony under Rules 402,

---

[7]Similar speculative inferences about intent appear throughout the challenged testimony. (*See* D.I. 293 at 15-18; D.I. 353 at 10-12; D.I. 294 Ex. 9; Tr. at 152-53.)

[8]Motions to exclude evidence are committed to the Court's discretion. *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 749 (3d Cir. 1994).

403, and 702 of the Federal Rules of Evidence and *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579 (1993). (D.I. 295) I will deny the motion with respect to paragraphs 209-217 of Dr. Roush's report and grant the motion with respect to paragraphs 218-229 of Dr. Roush's report.

Starting with paragraphs 209-217, Defendants' attempt to exclude is based on Defendants' interpretation of what constitutes the "closest prior art" to rosuvastatin calcium. The issue of what constitutes the "closest prior art" to rosuvastatin is an issue that Defendants' and Plaintiffs' experts hotly contest. In conducting the required analysis under Rule 702 and *Daubert*, it is not proper to attempt to assess the correctness of the expert's opinion. *See Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 449 F.3d 1209, 1221 (Fed. Cir. 2006); *In re Paoli,* 35 F.3d at 744 ("The evidentiary requirement of reliability is lower than the merits standard of correctness."). Defendants' criticisms can be adequately explored during cross-examination of the experts at trial, allowing the trier of fact to evaluate the weight to be given to the experts' testimony as to what constitutes the "closest prior art" to rosuvastatin calcium. Thus, I will deny the motion to exclude this portion of the report.

With respect to paragraphs 218-229 of Dr. Roush's report, however, I will grant the motion to exclude, for the same reasons I am excluding Hino's report and testimony. Plaintiffs have offered that: "The Shionogi scientists' research and development leading to the invention of rosuvastatin, as well as their knowledge and understanding of references that they are accused of intentionally withholding, are relevant to assist the trier of fact to understand the evidence and to determine whether Dr. Hirai knowingly withheld a material reference with an intent to deceive the USPTO." (D.I. 327 at 2-3) Plaintiffs add that "Dr. Hirai's knowledge and understanding of the references that he is accused of intentionally withholding is an issue of fact to be decided in the

case. Shionogi's invention story provides context to his actions." (*Id.* at 16) As with the excluded Hino testimony, however, this portion of Dr. Roush's report constitutes impermissible expert opinion as to the intent of an individual accused of deceiving the PTO. Thus, I likewise will exclude this portion of Dr. Roush's proffered testimony.

RECOMMENDED DISPOSITION AND ORDER

For the reasons set forth above:

1. I recommend that Aurobindo's Subject Matter Jurisdiction Motion (D.I. 277) be DENIED.

2. I recommend that Aurobindo's Personal Jurisdiction Motion (D.I. 275) be DENIED.

3. I recommend that the Court DENY Apotex's Motion to Dismiss or Transfer (D.I. 307), to the extent that it requests dismissal of the action. I further recommend that, to the extent that Apotex Inc. does not consent to personal jurisdiction in this matter in the District of Delaware, the Court transfer the cause of action as to Apotex Inc. to the Southern District of Florida.

4. Apotex Inc.'s request to strike Plaintiffs' Exhibit 61 (D.I. 369) is DENIED AS MOOT.

5. I recommend that Plaintiffs' No Inequitable Conduct Motion (D.I. 281) be DENIED.

5. Defendants' Motion to Exclude Hino's Testimony (D.I. 292) is GRANTED.

6. Defendants' Motion to Exclude Roush's Testimony (D.I. 295) is denied in part,

and granted in part. The motion is DENIED with respect to paragraphs 209-217 of Dr. Roush's report, and GRANTED with respect to paragraphs 218-229 of Dr. Roush's report.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections **of no longer than ten (10) pages within fourteen (14) days after being served with a copy of this Report and Recommendation**. Fed. R. Civ. P. 72(b). The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987); *Sincavage v. Barnhart*, 171 Fed. Appx. 924, 925 n.1 (3d Cir. 2006). **A party responding to objections may do so within fourteen (14) days after being served with a copy of objections; such response shall not exceed ten (10) pages. No further briefing shall be permitted with respect to objections without leave of the Court.**

The parties are directed to the Court's Standing Order In Non-*Pro Se* Matters For Objections Filed Under Fed. R. Civ. P. 72, dated November 16, 2009, a copy of which is available on the Court's website, www.ded.uscourts.gov/StandingOrdersMain.htm.

Dated: December 11, 2009
Wilmington, Delaware

The Honorable Leonard P. Stark
UNITED STATES MAGISTRATE JUDGE